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10/574,201	03/31/2006	Hiroyuki Sugawara	1034509-000002	8956

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EXAMINER

MARCETICH, ADAM M

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3761

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/574,201	Applicant(s) SUGAWARA, HIROYUKI	
	Examiner Adam Marcetich	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>31 March 2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. PCT/JP04/14203, filed on 29 September 2004.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 5, 6, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Johnson et al. (US Patent 5,180,504).
4. Regarding claims 1 and 2, Johnson discloses a method for blood treatment system having a primary bag holding collected blood (column 4, lines 13-24 and Fig. 6, element 16), a secondary bag holding filtered blood products (column 7, lines 15-22 and Fig. 6, element 34), connecting a first tube to the primary and secondary bags (column 6, lines 51-60 and Fig. 6, element 68), a filter unit connected to the bags, said filter unit having a filter medium for removing specific components (column 6, lines 14-19 and Fig. 2, elements 40 and 44, respectively), the filter also having inlet and outlet ports (Fig. 6,

upper and lower ends of element 40), and a second tube connected to the filter inlet and outlet (column 7, lines 47-59, especially lines 47-50 and Fig. 6, vent line 63 as labeled in Fig. 4). Johnson further discloses the step of using an apparatus for aseptically connecting the first tube to the second tube (column 6, lines 61-68 through column 7, lines 1-14 and Fig. 6, elements 66a and 66b). Johnson further discloses the entire system as being a sterile system (column 6, lines 30-36). Since the circuit must be assembled in order to function, Johnson substantially provides a method of assembling the circuit. Therefore, Johnson's device carries out the process during normal operation and thus anticipates the process, see MPEP 2112.02.

5. Regarding claims 5 and 6, Johnson discloses a connector system as previously discussed (Fig. 6, elements 66a and 66b), which substantially marks the position of connection.

6. Regarding claim 9, Johnson discloses the connector system as previously discussed in paragraph 4 above. The connector of Johnson is capable of showing which direction fluid flows through the connector, by printing or drawing on the connector. Examiner takes official notice that markings to show directional flow are well known in the art. For example, Teirstein (US Patent 5,779,666) uses arrows to indicate flow directions in one-way valves (Fig. 2, elements 36 and 58).

7. Regarding claim 10, Johnson discloses a method of assembling as previously discussed in paragraph 4 above, comprising connectors 66a and 66b. With regard to a mark, the connectors form a correct connection after heating (column 7, lines 3-14), substantially forming a mark that indicates correct connection. When the connectors of

Johnson are heat-sealed, a correct connection is formed. Therefore, the connectors 66a and 66b are inherently capable of indicating that the tubes have been correctly connected as claimed.

Claim Rejections - 35 USC § 102 / 103

8. Claims 11, 14-19 and 21-23 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Johnson.

9. Regarding claims 11 and 18, the language “formed by expanding” represents a product-by-process limitation. Johnson anticipates the claimed device with a filter and connectors 66a and 66b as discussed in paragraph 4 above, no matter by what process it was made.

10. Regarding claim 14, Johnson discloses a filter as discussed in paragraph 4 above, having an inlet and outlet, filter medium for removing specific components, and tube connecting the inlet and outlet. Johnson further discloses tubing made from PVC (column 4, lines 42-46), a plastic capable of being cut, melted and aseptically connected. Therefore, the filter of Johnson is capable of being put to use by cutting the tube midway and aseptically connecting it to another tube.

Because of the nature of product-by process claims, the Examiner cannot ordinarily focus on the precise difference between the claimed process of putting a filter

Art Unit: 3761

to use and the disclosed filter. It is then Applicants' burden to prove that an unobvious difference exists. See In re Marosi, 218 USPQ 289, 292-293 (CAFC 1983).

In the instant case no Graham vs. John Deere analysis was made but rather the test set out in MPEP 706.03(e) and In re Marosi was applied while explaining why the claimed product does not patentably distinguish over the prior art under 35 USC 102/103.

11. Regarding claim 15, Johnson discloses a filter and connector system as previously discussed in paragraph 4 above. This connector substantially marks the position of connection.

12. Regarding claim 16, Johnson discloses a filter and connector system as previously discussed in paragraph 4 above. The connector of Johnson is capable of showing which direction fluid flows through the connector, by printing or drawing on the connector. With respect to rationale, see paragraph 6 above.

13. Regarding claim 17, Johnson discloses a filter and connector system as previously discussed in paragraph 4 above. The connector system of Johnson is also capable of showing a correct connection as discussed in paragraph 7 above.

14. Regarding claim 19, Johnson discloses a tube connecting the primary bag to the secondary bag as discussed in paragraph 4 above. Since the tubes of Johnson are made of PVC as discussed in paragraph 10 above, they are also capable of being connected by cutting and aseptically connecting.

15. Regarding claim 21, Johnson discloses a connector system as previously discussed in paragraph 4 above, having a tube bypassing the filter (column 7, lines 47-59, especially lines 47-50 and Fig. 6, vent line 63 as labeled in Fig. 4).

16. Regarding claim 22, Johnson discloses a filter as discussed in paragraph 4 above, having an inlet and outlet, filter medium and tube connecting the inlet and outlet.

17. Regarding claim 23, Johnson discloses a filter as discussed in paragraph 4 above. Johnson further discloses a connector system capable of indicating a correct connection to a user as discussed in paragraph 7 above. With respect to rationale, see paragraph 7 above.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

20. Claims 3, 4, 7, 8 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson in view of Fell (US Patent 6,733,433).

21. Regarding claims 3 and 4, Johnson discloses a method of assembling blood treatment circuit as discussed in paragraph 4 above. Johnson lacks a plurality of secondary bags, a first tube connecting a primary bag to secondary bags and a third tube connecting secondary bags to each other. Fell discloses a plurality of secondary bags for holding stem-cells, plasma and red cells (column 6, lines 66-67 through column 7, lines 1-2, column 8, lines 59-63 and Fig. 3, elements 42-44 respectively) and a first tube connecting the primary bag to the plurality of secondary bags (Fig. 3, tubing between elements 46 and 47) under sterile conditions (column 3, lines 19-24). Fell further discloses a third tube connecting secondary bags to each other (Fig. 3, lines between elements 42, 43 and 44).

Fell discloses a treatment system for separating blood components (column 1, lines 15-22), having a filter (column 6, lines 60-66 and Fig. 3, element 54). Fell provides the ability to separate hematopoietic stem cells (column 2, lines 52-57). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the treatment system of Johnson as with the multiple bags and tubes of Fell as discussed in order to provide additional containers for blood components as provided by Fell.

22. Regarding claims 7 and 8, Johnson discloses a connector system as previously discussed (Fig. 6, elements 66a and 66b), which substantially mark the position of connection.

23. Regarding claim 20, Johnson discloses a filter and connector as discussed in paragraph 4 above. Johnson lacks a tube connecting a plurality of second bags to each other. Fell discloses a plurality of bags and tubing connecting the bags to each other as discussed in paragraph 21 above. With respect to motivation, see paragraph 21 above.

The tubes of Johnson are made of PVC as discussed in paragraph 10 above. Fell also discloses the capability of aseptically connecting tubes (column 7, lines 66-67). Therefore, the tubes are also capable of being connected by cutting and aseptically connecting as discussed in paragraph 10 above.

24. Claims 12, 13, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson in view of Minshall et al. (US Patent 5,496,302). Johnson discloses method of assembling a circuit, comprising a filter as discussed in paragraph 4 above. Johnson lacks the step of sterilizing a filter under different conditions with respect to a bag set. Minshall discloses a method of separately sterilizing components in a medical liquid handling system (column 2, lines 28-38). Minshall further discloses sterilizing a liquid handling component by irradiation (column 5, lines 55-57), and preferably sterilizing the liquid containers with steam heat (column 5, lines 51-54), to prevent deleterious effects of radiation on the container contents (column 5, lines 48-50). Minshall uses a blood apheresis system as an example, without limiting the scope

Art Unit: 3761

to apheresis systems (column 4, lines 52-56). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the invention of Johnson as discussed in paragraph 4 above with the method of sterilizing components separately of Minshall in order to prevent deleterious effects as called for by Minshall.

Conclusion

25. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Sano (US Patent 5,802,689)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Marcetich whose telephone number is 571-272-2590. The examiner can normally be reached on 8:00am to 4:30pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3761

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Adam Marcetich
Examiner
Art Unit 3761



AMM 5/11/07

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

